



Express Mail Mailing Label No.: EV334240785US

PATENT

Attorney Docket No. LEX-003

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT(S): Gillies *et al.* CONFIRMATION NO.: 9492  
SERIAL NO.: 09/256,156 GROUP NO.: 1647  
FILING DATE: February 24, 1999 EXAMINER: Kapust, R.B.  
TITLE: Enhancing the Circulating Half Life of Antibody-Based Fusion Proteins

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

**REMARKS**

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☐ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☒ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☒ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or

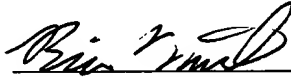
- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

Respectfully submitted,

Date: July 8, 2004  
Reg. No. 48,645

Tel. No.: (617) 248-7697  
Fax No.: (617) 248-7100

  
\_\_\_\_\_  
Brian A. Fairchild  
Attorney for the Applicants  
Testa, Hurwitz, & Thibeault, LLP  
High Street Tower  
125 High Street  
Boston, Massachusetts 02110



FORM PTO - 1449

SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: LEX-003

APPLICANT(S): Gillies *et al.*

SERIAL NO.: 09/256,156

FILING DATE: February 24, 1999 GROUP: 1647

## U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A95	5,601,819	2/11/97	Wong et al.			
	A96	5,624,821	4/29/97	Winter et al.			
	A97	5,679,543	10/21/97	Lawlis			
	A98	5,891,680	4/6/99	Lieschke et al.			
	A99	5,994,104	11/30/99	Anderson et al.			
	A100	6,429,199	8/6/02	Krieg et al.			
	A101	6,551,592	4/22/03	Lindhofer et al.			
	A102	6,646,113	11/11/03	Dreyfuss et al.			
	A103	2002/0037558	3/28/02	Lo et al.			
	A104	2002/0146388	10/10/02	Gillies			
	A105	2003/0139365	7/24/03	Lo et al.			
	A106	2003/0139575	7/24/03	Gillies			
	A107	2004/0033210	2/19/04	Gillies			
	A108	2004/0053366	3/18/04	Lo et al.			
	A109	2004/0072299	4/15/04	Gillies et al.			
	A110	2004/0082039	4/29/04	Gillies et al.			

## FOREIGN PATENT DOCUMENTS

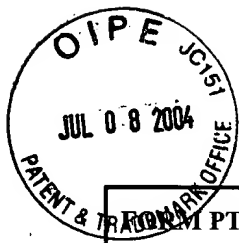
EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B106	WO 93/20185	10/14/93	PCT					
	B107	WO 97/43316	11/20/97	PCT					

EXAMINER

DATE CONSIDERED



FORM PTO - 1449		ATTORNEY DOCKET NO.: LEX-003
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		APPLICANT(S): Gillies <i>et al.</i>
		SERIAL NO.: 09/256,156
		FILING DATE: February 24, 1999 GROUP: 1647
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C236	Batra et al., (1993), "Insertion of Constant Region Domains of Human IgG1 into CD4-PE40 Increases Its Plasma Half-Life," <u>Molecular Immunology</u> , 30(4):379-386.
	C237	Chapman et al., (1994), "Mapping Effector Functions of a Monoclonal Antibody to GD3 by Characterization of a Mouse-Human Chimeric Antibody," <u>Cancer Immuno. Immunother.</u> , 39:198-204.
	C238	Cruse et al., (eds.), (1995), <u>Illustrated Dictionary of Immunology</u> , p.158, CRC Press, NY.
	C239	de la Salle et al., (1996), "FcγR on Human Dendritic Cells," in <u>Human IgG Receptors</u> , pp. 39-55, van de Winkel et al. (eds.), R.G. Landes Co.
	C240	Dorai et al., (1991), "Aglycosylated Chimeric Mouse/Human IgG1 Antibody Retains Some Effector Function," <u>Hybridoma</u> , 10(2):211-217.
	C241	Dorai et al., (1992), "Role of Inter-Heavy and Light Chain Disulfide Bonds in the Effector Functions of Human IgG1," <u>Molecular Immunology</u> , 29(12):1487-1491.
	C242	Elliott et al., (1996), "Fine-Structure Epitope Mapping of Antierythropoietin Monoclonal Antibodies Reveals a Model of Recombinant Human Erythropoietin Structure," <u>Blood</u> , 87(7):2702-2713.
	C243	Gillies et al., (1991), "Targeting Human Cytotoxic T Lymphocytes to Kill Heterologous Epidermal Growth Factor Receptor-Bearing Tumor Cells: Tumor-Infiltrating Lymphocyte/Hormone Receptor/Recombinant Antibody," <u>J. Immunology</u> , 146(3):1067-1071.
	C244	Handgretinger et al., (1995), "A Phase I Study of Human/Mouse Chimeric Anti-ganglioside GD2 Antibody ch14.18 in Patients with Neuroblastoma," <u>European J. Cancer</u> , 31A(2):261-267.
	C245	Harvill et al., (1995), "An IgG3-IL2 Fusion Protein Activates Complement, Binds FcγRI, Generates LAK Activity and Shows Enhanced Binding to the High Affinity IL-2R," <u>Immunotechnology</u> , 1:95-105.
	C246	Harvill et al., (1996), "In Vivo Properties of an IgG3-IL-2 Fusion Protein: A General Strategy for Immune Potentiation," <u>J. Immunology</u> , 157(7):3165-3170.
	C247	Hurn et al., (1980), "Production of Reagent Antibodies," <u>Methods in Enzymology</u> , 70: 104-142.
	C248	Isenman et al., (1975), "The Structure and Function of Immunoglobulin Domains: II. The Importance of Interchain Disulfide Bonds and the Possible Role of Molecular Flexibility in the Interaction between Immunoglobulin G and Complement," <u>J. Immunology</u> , 114(6):1726-1729.
	C249	Lo et al., (1992), "Expression and Secretion of an Assembled Tetrameric CH2-deleted Antibody in <i>E. Coli.</i> ," <u>Hum. Antibod. Hybridomas</u> , 3:123-128.
	C250	Maecker et al., (1997), "DNA Vaccination with Cytokine Fusion Constructs Biases the Immune Response to Ovalbumin," <u>Vaccine</u> , 15(15):1687-1696.
EXAMINER		DATE CONSIDERED



PTO - 1449		ATTORNEY DOCKET NO.: LEX-003	
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		APPLICANT(S): Gillies <i>et al.</i>	
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EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)		
	C251	Mueller et al., (1990), "Enhancement of Antibody-Dependent Cytotoxicity With A Chimeric Anti-GD2 Antibody," <u>J. Immunology</u> , 144(4):1382-1386	
	C252	Mueller et al., (1990), "Serum Half-Life and Tumor Localization of a Chimeric Antibody Deleted of the CH2 Domain and Directed Against the Disialoganglioside GD2," <u>Proc. Natl. Acad. Sci. USA.</u> , 87:5702-5705.	
	C253	Naramura et al., (1993), "Therapeutic Potential of Chimeric and Murine Anti-(Epidermal Growth Factor Receptor) Antibodies in a Metastasis Model for Human Melanoma," <u>Cancer Immuno. Immunother.</u> , 37:343-349.	
	C254	Reisfeld et al., (1994), "Potential of Genetically Engineered Anti-Ganglioside GD2 Antibodies for Cancer Immunotherapy," <u>Prog. Brain Res.</u> , 101:201-212	
	C255	Saleh et al., (1992), "Phase I Trial of the Chimeric Anti-GD2 Monoclonal Antibody ch14.18 in Patients With Malignant Melanoma," <u>Hum. Antibod. Hybridomas</u> , 3:19-24.	
	C256	Sallusto et al., (1994), "Efficient Presentation of Soluble Antigen by Cultured Human Dendritic Cells Is Maintained by Granulocyte/Macrophage Colony-stimulating Factor Plus Interleukin 4 and Downregulated by Tumor Necrosis Factor $\alpha$ ," <u>J. Exp. Med.</u> , 179:1109-1118.	
	C257	Schlom (1991), "Monoclonal Antibodies: They're More and Less Than You Think," in <u>Molecular Foundations of Oncology</u> , pp. 95-133.	
	C258	Wen et al., (1994), "Erythropoietin Structure-Function Relationships: Identification of Functionally Important Domains," <u>J. Biological Chemistry</u> , 269(36):22839-22846.	
	C259	Xu et al., (1994), "Residue at Position 331 in the IgG1 and IgG4 CH2 Domains Contributes to Their Differential Ability to Bind and Activate Complement," <u>J. Biol. Chem.</u> , 269(5):3469-3474.	
EXAMINER		DATE CONSIDERED	

	<b>Complete if Known</b>	
	Application Serial Number	09/256,156
	Filing Date	February 24, 1999
	First Named Inventor	Gillies
	Group Art Unit	1647
	Examiner Name	Kapust, R.B.
	Attorney Docket No.	LEX-003

METHOD OF PAYMENT				FEE CALCULATION (continued)																																																																																							
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2. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to credit or charge any fee indicated below for this submission to Deposit Account No. 20-0531. <input type="checkbox"/> Required Fees (copy of this sheet enclosed). <input checked="" type="checkbox"/> Additional fee required under 37 CFR 1.16 and 1.17. <input checked="" type="checkbox"/> Overpayment Credit.				<table border="1"> <thead> <tr> <th>Large Entity Fee (\$)</th> <th>Small Entity Fee (\$)</th> <th>Fee Description</th> <th>Fee Paid</th> </tr> </thead> <tbody> <tr> <td>130</td> <td>65</td> <td>Surcharge - late filing fee or oath</td> <td></td> </tr> <tr> <td>50</td> <td>25</td> <td>Surcharge - late provisional filing fee or cover sheet</td> <td></td> </tr> <tr> <td>130</td> <td>130</td> <td>Non-English specification</td> <td></td> </tr> <tr> <td>2,520</td> <td>2,520</td> <td>Request for ex parte reexamination</td> <td></td> </tr> <tr> <td>110</td> <td>55</td> <td>Extension for reply within first month</td> <td></td> </tr> <tr> <td>420</td> <td>210</td> <td>Extension for reply within second month</td> <td></td> </tr> <tr> <td>950</td> <td>475</td> <td>Extension for reply within third month</td> <td></td> </tr> <tr> <td>1480</td> <td>740</td> <td>Extension for reply within fourth month</td> <td></td> </tr> <tr> <td>2010</td> <td>1005</td> <td>Extension for reply within fifth month</td> <td></td> </tr> <tr> <td>330</td> <td>165</td> <td>Notice of Appeal</td> <td></td> </tr> <tr> <td>330</td> <td>165</td> <td>Filing a brief in support of an appeal</td> <td></td> </tr> <tr> <td>290</td> <td>145</td> <td>Request for oral hearing</td> <td></td> </tr> <tr> <td>130</td> <td>130</td> <td>Petitions to the Commissioner</td> <td></td> </tr> <tr> <td>180</td> <td>180</td> <td>Submission of Information Disclosure Statement</td> <td>180.00</td> </tr> <tr> <td>770</td> <td>385</td> <td>Filing a submission after final rejection (37 CFR 1.129(a))</td> <td></td> </tr> <tr> <td>770</td> <td>385</td> <td>For each additional invention to be examined (37 CFR 1.129(b))</td> <td></td> </tr> <tr> <td>100</td> <td>100</td> <td>Certificate of Correction for applicant's error</td> <td></td> </tr> <tr> <td>110</td> <td>55</td> <td>Submission of Terminal Disclaimer</td> <td></td> </tr> <tr> <td colspan="2">Other fee (Specify)</td> <td colspan="2"></td> </tr> <tr> <td colspan="2">Other fee (Specify)</td> <td colspan="2"></td> </tr> </tbody> </table>				Large Entity Fee (\$)	Small Entity Fee (\$)	Fee Description	Fee Paid	130	65	Surcharge - late filing fee or oath		50	25	Surcharge - late provisional filing fee or cover sheet		130	130	Non-English specification		2,520	2,520	Request for ex parte reexamination		110	55	Extension for reply within first month		420	210	Extension for reply within second month		950	475	Extension for reply within third month		1480	740	Extension for reply within fourth month		2010	1005	Extension for reply within fifth month		330	165	Notice of Appeal		330	165	Filing a brief in support of an appeal		290	145	Request for oral hearing		130	130	Petitions to the Commissioner		180	180	Submission of Information Disclosure Statement	180.00	770	385	Filing a submission after final rejection (37 CFR 1.129(a))		770	385	For each additional invention to be examined (37 CFR 1.129(b))		100	100	Certificate of Correction for applicant's error		110	55	Submission of Terminal Disclaimer		Other fee (Specify)				Other fee (Specify)			
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Direct all correspondence to: Patent Administrator Testa, Hurwitz & Thibault, LLP High Street Tower-125 High Street Boston, MA 02110 Tel. No.: (617) 248-7000 Fax No.: (617) 248-7100				Respectfully submitted,  Date: July 8, 2004 Reg. No.: 48,645 Tel. No.: (617) 248-7697 Fax No.: (617) 248-7100 Brian A. Fairchild Attorney for the Applicants Testa, Hurwitz & Thibault, LLP High Street Tower-125 High Street Boston, MA 02110																																																																																							